

WHAT IS CLAIMED IS:

1 1. An apparatus for collection and lateral flow chromatography of an
2 oral fluid, the apparatus comprising:
3 a lateral flow chromatography strip including a receiving area;
4 a capillary matrix having a surface; and
5 a bite portion coupled to the capillary matrix and insertable between
6 teeth of a subject to position the surface of the capillary matrix for receiving an oral fluid of
7 the subject, the capillary matrix being in communication with the lateral flow
8 chromatography strip to wick up and deliver the received oral fluid to the receiving area of
9 the lateral flow chromatography strip.

1 2. The apparatus of claim 1, wherein the bite portion positions the
2 capillary matrix in a buccal space of the subject.

1 3. The apparatus of claim 1, wherein the capillary matrix is sheet-like in
2 shape and the bite portion comprises a bite plate disposed substantially perpendicular to the
3 capillary matrix.

1 4. The apparatus of claim 1, wherein the bite portion comprises textured
2 surfaces for contacting the teeth.

1 5. The apparatus of claim 1, wherein the bite portion comprises a saliva-
2 stimulating substance.

1 6. The apparatus of claim 5, wherein the saliva-stimulating substance is
2 selected from the group consisting of citric acid, tartaric acid, fumaric acid, ascorbic acid,
3 malic acid, salt, fructose, glucose, sucrose, and artificial sweetener, and aromatic compound.

1 7. The apparatus of claim 1, wherein the bite portion is insertable
2 between the teeth of the subject to contact a tongue of the subject.

1 8. The apparatus of claim 1, wherein the bite portion is insertable
2 between the teeth in proximity to the tongue of the subject

1 9. The apparatus of claim 1, further comprising a housing having a
2 cavity in which the lateral flow chromatography strip is at least partially disposed.

1 10. The apparatus of claim 9, wherein the housing includes at least one
2 inspection site providing visual inspection of reagents at selected sites on the lateral flow
3 chromatography strip.

1 11. The apparatus of claim 9, wherein the housing is connected to the bite
2 portion.

1 12. The apparatus of claim 9, wherein the housing is connected to the
2 capillary matrix.

1 13. The apparatus of claim 9, wherein the capillary matrix is insertable
2 partially into the cavity of the housing which acts as a handle for inserting the capillary
3 matrix into an oral cavity of the subject.

1 14. The apparatus of claim 1, wherein the lateral flow chromatography
2 strip includes lateral flow chromatography reagents.

1 15. The apparatus of claim 1, further comprising a conjugate strip coupled
2 between the capillary matrix and the lateral flow chromatography strip and including lateral
3 flow chromatography reagents.

1 16. The apparatus of claim 1, further comprising a blocking strip coupled
2 between the capillary matrix and the lateral flow chromatography strip and including a
3 detergent.

1 17. The apparatus of claim 16, wherein the blocking strip further includes
2 a buffer.

1 18. The apparatus of claim 1, further comprising an absorbent material
2 coupled near an end of the lateral flow chromatography strip opposite from the capillary
3 matrix.

1 19. The apparatus of claim 1, further comprising a cover for protecting the
2 capillary matrix.

1 20. The apparatus of claim 1, wherein saturation of the capillary matrix
2 with an oral fluid does not substantially alter the morphology of said capillary matrix.

1 21. The apparatus of claim 20, wherein saturation of the capillary matrix
2 with an oral fluid does not substantially alter the average pore size of said capillary matrix.

1 22. The apparatus of claim 20, wherein saturation of the capillary matrix
2 with an oral fluid does not substantially alter the void volume of said capillary matrix.

1 23. The apparatus of claim 20, wherein the capillary matrix has an
2 average pore size ranging from about 40 μm to about 250 μm .

1 24. The apparatus of claim 20, wherein the capillary matrix has a void
2 volume of less than about 60 μL .

1 25. The apparatus of claim 1, wherein the capillary matrix comprises a
2 plastic.

1 26. The apparatus of claim 25, wherein the capillary matrix comprises a
2 plastic selected from the group consisting of a polyethylene (PE), a polyester, a polystyrene,
3 a high density polyethylene (HDPE), an ultra-high molecular weight polyethylene (UHMW),
4 a polypropylene (PP), a polyvinylidene fluoride (PVDF), a polytetrafluoroethylene (PTFE),
5 a nylon 6 (N6), and a polyethersulfone (PES).

1 27. The apparatus of claim 25, wherein the plastic is hydrophilic or
2 treated to be hydrophilic.

1 28. The apparatus of claim 1, wherein the capillary matrix, when
2 contacted to an oral mucosa takes up oral fluid from the subject and releases the oral fluid to
3 the receiving area of the lateral flow chromatography strip in under about 2 minutes.

1 29. The apparatus of claim 28, wherein the capillary matrix, when
2 contacted to an oral mucosa takes up oral fluid from the subject and releases the oral fluid to
3 the receiving area of the lateral flow chromatography strip in under about 30 seconds.

1 30. The apparatus of claim 28, wherein the capillary matrix is saturated
2 with oral fluid in under about 1 minute.

1 31. The apparatus of claim 1, wherein the capillary matrix is saturated by
2 less than about 300 μ L of oral fluid

1 32. The apparatus of claim 31, wherein the capillary matrix is saturated by
2 less than about 100 μ L of oral fluid.

1 33. The apparatus of claim 1, wherein the capillary matrix releases the
2 oral fluid to the receiving area of the lateral flow chromatography strip without compression
3 of the capillary matrix.

1 34. The apparatus of claim 33, wherein sufficient oral fluid is released to
2 saturate the receiving area.

1 35. An apparatus for collection and lateral flow chromatography of an
2 oral fluid, the apparatus comprising:
3 a lateral flow chromatography strip including a receiving area;
4 a bite portion insertable between teeth of a subject; and
5 collection means coupled to the bite portion to contact an oral mucosa
6 of the subject for receiving oral fluid of the subject, and in communication with the lateral
7 flow chromatography strip for wicking up and delivering the received oral fluid to the
8 receiving area of the lateral flow chromatography strip.

1 36. The apparatus of claim 35, wherein the bite portion comprises a
2 saliva-stimulating substance.

1 37. The apparatus of claim 35, wherein the bite portion is insertable
2 between the teeth of the subject to contact a tongue of the subject.

38. The apparatus of claim 35, wherein the bite portion is insertable between the teeth of the subject in proximity to a tongue of the subject.

39. The apparatus of claim 35, further comprising conjugate means, coupled between the collection means and the lateral flow chromatography strip, for providing lateral flow chromatography reagents.

40. The apparatus of claim 35, further comprising adjusting means, coupled between the collection means and the lateral flow chromatography strip, for adjusting a pH of the received oral fluid.

41. The apparatus of claim 35, further comprising blocking means, coupled between the collection means and the lateral flow chromatography strip, for blocking unwanted substances from the collection means.

42. The apparatus of claim 35, further comprising blocking means, coupled between the collection means and the lateral flow chromatography strip, for preventing backflow of reagents or oral fluid from the lateral flow chromatography strip to the collection means.

43. The apparatus of claim 35, further comprising absorbent means coupled to the lateral flow chromatography strip for receiving the oral fluid from the collection means to prevent backflow thereof to the collection means.

44. The apparatus of claim 35, wherein the bite portion is held in place by occlusal force of the teeth to position the collection means for receiving the oral fluid.

45. A method of detecting an analyte in oral fluid of a subject, said method comprising:
inserting the apparatus of claim 1 or claim 35 into the oral cavity of said subject such that said bite portion is held between the teeth of said subject;
retaining said apparatus in said oral cavity until an oral fluid sample is collected; and
reading the presence or absence of said analyte from an indicator region on said apparatus.

1 46. A kit for detection of an analyte in oral fluid of a subject, said kit
2 comprising a container containing the apparatus of claim 1 or the apparatus of claim 35.

1 47. The kit of claim 46, further comprising instructional materials
2 describing the use of said apparatus for detecting said analyte.